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Description

[0001] This invention is directed to a device for penetrating body tissues for medical purposes such as tissue ablation and fluid substance delivery, for example. The device penetrates tissue to the precise target selected in order to deliver energy to the tissue and/or deliver substances. It limits this treatment to the precise preselected site, thereby minimizing trauma to normal surrounding tissue and achieving a greater medical benefit. This device is a catheter-like device for positioning a treatment assembly in the area or organ selected for medical treatment with one or more stylets in the catheter, mounted for extension from a stylet port in the side of the catheter through surrounding tissue to the tissue targeted for medical intervention.

[0002] Treatment of cellular tissues usually requires direct contact of target tissue with a medical instrument, usually by surgical procedures exposing both the target and intervening tissue to substantial trauma. Often, precise placement of a treatment probe is difficult because of the location of targeted tissues in the body or the proximity of the target tissue to easily damaged, critical body organs, nerves, or other components.

[0003] Benign prostatic hypertrophy or hyperplasia (BPH), for example, is one of the most common medical problems experienced by men over 50 years old. Urinary tract obstruction due to prostatic hyperplasia has been recognized since the earliest days of medicine. Hyperplastic enlargement of the prostate gland often leads to compression of the urethra, resulting in obstruction of the urinary tract and the subsequent development of symptoms including frequent urination, decrease in urinary flow, nocturia, pain, discomfort, and dribbling. The association of BPH with aging has been shown to exceed 50% in men over 50 years of age and increases in incidence to over 75% in men over 80 years of age. Symptoms of urinary obstruction occur most frequently between the ages of 65 and 70 when approximately 65% of men in this age group have prostatic enlargement.

[0004] Currently there is no proven effective non-surgical method of treatment of BPH. In addition, the surgical procedures available were not totally satisfactory. Patients suffering from the obstructive symptoms of this disease were provided with few options: continue to cope with the symptoms (i.e., conservative management), submit to drug therapy at early stages, or submit to surgical intervention. More than 430,000 patients per year undergo surgery for removal of prostatic tissue in the United States. These represent less than five percent of men exhibiting clinical significant symptoms.

[0005] Those suffering from BPH are often elderly men, many with additional health problems which increase the risk of surgical procedures. Surgical procedures for the removal of prostatic tissue were associated with a number of hazards including anesthesia related morbidity, hemorrhage, coagulopathies, pulmonary emboli and electrolyte imbalances. These procedures performed currently can also lead to cardiac complications, bladder perforation, incontinence, infection, urethral or bladder neck stricture, retention of prostatic chips, retrograde ejaculation, and infertility. Due to the extensive invasive nature of the treatment options for obstructive uropathy, the majority of patients delay definitive treatment of their condition. This circumstance can lead to serious damage to structures secondary to the obstructive lesion in the prostate (bladder hypertrophy, hydronephrosis, dilation of the kidney pelves, chronic infection, dilation of ureters, etc.) which is not without significant consequences. In addition, a significant number of patients with symptoms sufficiently severe to warrant surgical intervention are therefore poor operative risks and are poor candidates for prostatectomy. In addition, younger men suffering from BPH who do not desire to risk complications such as infertility are often forced to avoid surgical intervention. Thus the need, importance and value of improved surgical and non-surgical methods for treating BPH is unquestionable.

[0006] High-frequency currents are used in electrocautery procedures for cutting human tissue especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated.

[0007] Destruction of cellular tissues *in situ* has been used in the treatment of many diseases and medical conditions alone or as an adjunct to surgical removal procedures. It is often less traumatic than surgical procedures and may be the only alternative where other procedures are unsafe. Ablative treatment devices have the advantage of using an electromagnetic energy which is rapidly dissipated and reduced to a non-destructive level by conduction and convection forces of circulating fluids and other natural body processes.

[0008] Microwave, radiofrequency, acoustical (ultrasound) and light energy (laser) devices, and tissue destructive substances have been used to destroy malignant, benign and other types of cells and tissues from a wide variety of anatomic sites and organs. Tissues treated include isolated carcinoma masses and, more specifically, organs such as the prostate, glandular and stromal nodules characteristic of benign prostate hyperplasia. These devices typically include a catheter or cannula which is used to carry a radiofrequency electrode or microwave antenna through a duct to the zone of treatment and apply energy diffusely through the duct wall into the surrounding tissue in all

directions. Severe trauma is often sustained by the duct wall during this cellular destruction process, and some devices combine cooling systems with microwave antennas to reduce trauma to the ductal wall. For treating the prostate with these devices, for example, heat energy is delivered through the walls of the urethra into the surrounding prostate cells in an effort to ablate the tissue causing the constriction of the urethra. Light energy, typically from a laser, is delivered to prostate tissue target sites by "burning through" the wall of the urethra. Healthy cells of the duct wall and healthy tissue between the nodules and duct wall are also indiscriminately destroyed in the process and can cause unnecessary loss of some prostate function. Furthermore, the added cooling function of some microwave devices complicates the apparatus and requires that the device be sufficiently large to accommodate this cooling system.

[0009] More specifically in the prior art, US-A-4,565,200 discloses a radio frequency lesion electrode system having an insulated outer cannula through which the electrodes are fed. Temperature sensors may be provided. WO-A-92/10142 uses laser energy to treat tissue, the laser energy being supplied to the end of a catheter and needle system. Various lumina in the catheter terminate at the surface of the catheter. US-A-4,950,267 discloses a laser beam treatment device for an endoscope comprising a control section and an insertion section which includes a flexible tube portion, a bending portion and a distal end portion. EP-A-0521595 shows a torqueable catheter, through the lumen of which electrodes may be passed for treating tissues at the end of the catheter. The intermediate document WO-A-94/04220 discloses a medical probe device as defined in claim 1, in which, however, no second lumen is provided within the insulating sleeve.

[0010] Application of liquids to specific tissues for medical purposes is limited by the ability to obtain delivery without traumatizing intervening tissue and to effect a delivery limited to the specific target tissue. Localized chemotherapy, drug infusions, collagen injections, or injections of agents which are then activated by light, heat or chemicals would be greatly facilitated by a device which could conveniently and precisely place a fluid (liquid or gas) supply catheter opening at the specific target tissue.

OBJECTS AND SUMMARY OF THE INVENTION

[0011] It is an object of this invention to provide a device for penetrating tissue, through intervening tissues to the precise target tissue selected for a medical action such as tissue ablation and/or substance delivery, limiting this activity to the precise preselected site, thereby minimizing the trauma and achieving a greater medical benefit.

[0012] It is another object of this invention is to provide a device for tissue ablation of body tissues which delivers the therapeutic energy directly into targeted tissues while minimizing effects on its surrounding tissue.

[0013] It is a still further object of this invention is to provide a device for introducing fluid treatment agents such as flowable liquids and gases, with greater precision and ease to a specific location in the body.

[0014] Another object of this invention which may be embodied is to provide a thermal destruction device which gives the operator more information about the temperature and other conditions created in both the tissue targeted for treatment and the surrounding tissue. In addition, it will provide more control over the physical placement of the stylet and over the parameters of the tissue ablation process.

[0015] In summary, the medical probe device of this invention is as shown in claim 1. Preferably, at least one portion of an opposed surface of the electrode lumen and the electrode are spaced apart to define a liquid supply passageway for delivery of medicament liquid. A second optional fluid passage lumen terminates at a distal port in the distal end of the non-conductive sleeve and comprises means passing fluid therethrough.

[0016] A temperature sensor third lumen terminates in a sealed closure adjacent the distal end of the non-conductive sleeve. At least one and preferably a plurality of temperature sensing devices such as thermocouples are positioned in the third lumen, the leads extending through the lumen. One preferred embodiment has two temperature sensing devices positioned in the third lumen, one temperature sensing device being positioned within about 1 mm of the distal end of the non-conductive sleeve, and the second temperature sensing device being positioned at least 3 mm and preferably from 3 to 6 mm from the distal end of the non-conductive sleeve.

[0017] In summary, another embodiment of this invention comprises a catheter having a control end and a probe end, the probe end including a stylet guide housing having at a stylet port and stylet guide means for directing a flexible stylet outward through the stylet port and through intervening tissue to targeted tissues. A stylet is positioned in at least one of said stylet guide means, the stylet comprising an electrical conductor enclosed within a non-conductive sleeve. The electrode has a distal length having at least one current focusing groove means thereon and a distal tip shaped to focus current on its terminal end, whereby RF current passing therefrom into surrounding tissue forms a lesion extending outward from the groove and tip. In one preferred embodiment, the distal length has a plurality of annular focusing grooves or a spiral focusing groove thereon.

[0018] Preferably at least a part of the electrode is enclosed within a support tube having sufficient strength to maintain electrode linearity when the electrode is directed outward through the stylet port.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019]

Fig. 1 is an isometric view of an RF ablation catheter embodiment of this invention with an fiber optic viewing accessory.

Fig. 2 is a cross-sectional view of a catheter of Fig. 1 showing details of the stylet guide housing.

Fig. 3 is a side view of the stylet and lumen assembly of this invention.

Fig. 4 is a cross-sectional side view of the of the junction of the stylet and control tube assembly taken along the central axis of the tubing.

Fig. 5 is a cross-sectional view of the junction of the stylet and control tube assembly taken along the line 5-5 of Fig. 4.

Fig. 6 is a cross-sectional view of a trilumen stylet of this invention taken along the line 6-6 in Fig 3.

Fig. 7 is a cross-sectional side view of the trilumen stylet tip shown in Fig. 3 taken along line 7-7 of Fig. 6.

Fig. 8 is a plane view of the annular groove embodiment of the current density focusing electrode of this invention.

Fig. 9 is a plane view of the spiral groove embodiment of the current density focusing electrode of this invention. position and the sleeve partially retracted therefrom.

Fig. 10 is an exploded view of the RF ablation catheter shown in Fig. 1.

Fig. 11 is an isometric view of the adjuster block and tension tube assembly of the RF ablation catheter shown in Fig. 10.

Fig. 12 is a detailed view "A" of the tension tube connections shown in Fig. 11.

Fig. 13 is an exploded view of the sleeve and electrode slide block assembly of the embodiment shown in Fig. 10.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The device of this invention provides a precise controlled positioning of a treatment stylet in a tissue targeted for treatment, destruction or sampling from a catheter positioned in the vicinity of the target tissue.

[0021] The term "stylet" as used hereinafter is defined to include both solid and hollow probes which are adapted to be passed from a catheter port through normal tissue to targeted tissues. The stylet is shaped to facilitate easy passage through tissue. It can be a solid wire, thin rod, or other solid shape or it can be a thin hollow tube or other shape having a longitudinal lumen for introducing fluids to or removing materials from a site. The stylet can also be a thin hollow tube or other hollow shape, the hollow lumen thereof containing a reinforcing or functional rod or tube such as a laser fiber optic. The stylet preferably has a sharpened end to reduce resistance and trauma when it is pushed through tissue to a target site.

[0022] The stylet can be designed to provide a variety of medically desired treatments of a selected tissue. As a radiofrequency electrode or microwave antenna, it can be used to ablate or destroy targeted tissues. As a hollow tube, it can be used to deliver a treatment fluid such as a liquid to targeted tissues. The liquid can be a simple solution or a suspension of solids, for example, colloidal particles, in a liquid. Since the stylet is very thin, it can be directed from the catheter through intervening normal tissue with a minimum of trauma to the normal tissue.

[0023] The device of this invention provide a more precise, controlled medical treatment which is suitable for destroying cells of medically targeted tissues throughout the body, both within and external to body organs. The device are particularly useful for treating benign prostate hyperplasia (BPH), and the device and its use are hereinafter described with respect to BPH, for purposes of simplifying the description thereof. It will be readily apparent to a person skilled in the art that the device can be used to destroy body tissues in any body cavities or tissue locations that are accessible by percutaneous or endoscopic catheters, and is not limited to the prostate. Application of the device in all of these organs and tissues are intended to be included within the scope of this invention.

[0024] BPH is a condition which arises from the replication and growth of cells in the prostate and the decrease of cell death rate, forming glandular and stromal nodules which expand the prostate and constrict the opening of the prostatic urethra. Glandular nodules are primarily concentrated within the transition zone, and stromal nodules within the periurethral region. Traditional treatments of this condition have included surgical removal of the entire prostate gland, digital removal of the adenoma, as well as transurethral resection of the urethral canal and prostate to remove tissue and widen the passageway. One significant and serious complication associated with these procedures is iatrogenic sterility. More recently, laser treatment has been employed to remove tissue, limiting bleeding and loss of body fluids. Balloons have also been expanded within the urethra to enlarge its diameter, with and without heat, but have been found to have significant limitations.

[0025] Microwave therapy has been utilized with some success by positioning a microwave antenna within the prostatic urethra and generating heat in the tissue surrounding the urethra with an electromagnetic field. Coolants are sometimes applied within the catheter shaft to reduce the temperature of the urethral wall. This necessitates complicated mechanisms to provide both cooling of the immediately adjacent tissues while generating heat in the more distant prostatic tissue. This technique is similar to microwave hyperthermia. Similarly, radiofrequency tissue ablation with electrodes positioned within the urethra exposes the urethral wall

to destructive temperatures. To avoid this, low temperature settings required to protect the urethra must be so low that the treatment time required to produce any useful effect is unduly extended; e.g. up to three hours of energy application.

[0026] One embodiment of the device of this invention uses the urethra to access the prostate and positions RF electrode stylets directly into the tissues to be destroyed. The portion of the stylet conductor extending from the urethra to targeted tissues is enclosed within a longitudinally adjustable sleeve shield which prevents exposure of the tissue adjacent to the sleeve to the RF current. The sleeve movement is also used to control the amount of energy per unit surface area which is delivered by controlling the amount of electrode exposed. Thus the ablative destruction is confined to the tissues targeted for destruction, namely those causing the constriction. Other aspects of the invention will become apparent from the drawings and accompanying descriptions of the device of this invention. It will be readily apparent to a person skilled in the art that this procedure can be used in many areas of the body for approaches through body orifices.

[0027] Fig. 1 is an isometric view of an RF ablation catheter embodiment of this invention with a fiber optic viewing accessory. The flexible catheter 2, attached to handle 4, has a terminal stylet guide 6 with two stylets 8. The handle has stylet electrode tabs 10 and 11 and sleeve tabs 12 and 13 as will be described in greater detail hereinafter. The handle 4 is also connected to a optical viewing assembly 14 and RF power connector 16, transponder connector 18 and thermocouple connectors 20. The portions of the catheter 2 leading from the handle 4 to the stylet guide tip 6 can optionally has a graduated stiffness. For example, the catheter can be designed to be more stiff near the handle and more flexible near the tip, or any other stiffness profiles. The catheter can be constructed of an inner slotted stainless steel tube with outer flexible sleeve such as is described in U.S. Patent No. 5,322,064. It can also be made of coiled or braided wire to which an outer sleeve is bonded.

[0028] The fiber optic viewing assembly in this embodiment includes a lens focusing assembly 22, a lens viewing assembly support connector 24 assembly attached to a male quick disconnect connector 26 by flexible tubing 28.

[0029] Fig. 2 is a cross-sectional view of a catheter of Fig. 1 showing details of the stylet guide housing. The stylet guide housing 6 has a curved passageway 28 through which the stylet 8 is extended into the tissue to be treated. Further details of these components are described in copending applications Serial No. 08/012,370 filed February 2, 1993, corresponding to WO-A-940220 and WO-A-9417856.

[0030] Fig. 3 is a side view of the stylet and lumen assembly of this invention. The key components of the stylet of this embodiment are an insulating sleeve 30 and an electrode 32 extending therethrough. The electrode 32 has a sharpened tip, in this embodiment a broadened spear tip. The proximal end of the electrode and sleeve are connected by respective sleeve connector 334 and electrode connector 338 to handle sleeve and electrode slides described in greater detail hereinafter with respect to Figs. 10 and 13. An electrode support tube 36 extends from the electrode connector 338 to the area 38 of the sleeve connector 334 to transmit compressive pressure without collapsing the electrode 32. An insulating sleeve support tube 40 made of shrink tubing extends from the sleeve connector 334 to the beginning or proximal end 42 of the outer tubing 44. Tubing 44 joins the support tubing to the control tube 46. The control tube 46 supporting both the electrode and insulating sleeve extends to the junction 48 (see Fig. 4) of the electrode lumen passageway 50 and the electrode 32. In this manner, support is provided over the length of the stylet extending from the handle to the trilumen tip, preventing collapse or loss of linearity of the highly flexible electrode when it is pushed through the stylet guide housing.

[0031] Fig. 4 is a cross-sectional side view of the junction of the stylet and control tube assembly taken along the central axis of the tubing, and Fig. 5 is a cross-sectional view of the junction of the stylet and control tube assembly taken along the line 5-5 of Fig. 4. At the junction 48, the electrode 32 extends through the upper electrode lumen wall 62 and enters the electrode lumen 50. The outer tubing 52 encloses and supports both the distal ends of the control tubing 46 and trilumen sleeve tube 54.

[0032] Referring to Fig. 5, the space 56 between the control tube 46 and the trilumen sleeve tube 54 can be filled with an adhesive to secure them together. The trilumen includes an electrode lumen 50, a temperature sensor lumen 58 and a fluid supply lumen 60 for supply of optional fluids such as antibiotics or anesthetics to the area of treatment.

[0033] Fig. 6 is a cross-sectional view of a trilumen stylet of this invention taken along the line 6-6 in Fig 3. The trilumen sleeve 30 is an insulating sleeve for the electrode 32 and includes the additional temperature sensor lumen 58 and liquid supply lumen 60. The inner surface of the electrode lumen 50 can be spaced from the outer surface of the electrode by a distance "h" which can be, for example, from about 1 to 3 mm to define an additional liquid supply conduit with an approximate annular cross-section.

[0034] Fig. 7 is a cross-sectional side view of the trilumen stylet tip shown in Fig. 6 taken along the line 7-7. The terminal end of the temperature sensor lumen 58 is sealed to protect the electrical components. Thermocouple 64 is placed at the distal end of the sleeve 30 to monitor the temperature of the tissue surrounding the electrode 32 and is preferably less than about 1 mm from the exposed electrode. Thermocouple 66 is placed at least about 3 mm and preferably from about 3 to 6

mm from the tip of sleeve 30 to monitor the temperature of the duct wall (such as the urethra) through which the stylet is extended. This is provided to ensure the duct wall temperature does not reach destructive levels when the RF treatment of tissue surrounding the extended electrode is underway.

[0035] Fig. 8 is a plane view of the annular groove embodiment of the current density focusing electrode of this invention. In this embodiment, the electrode is ground to a single current focusing sharp tip 68 without secondary corner or other sharp edges which could also focus or crowd current. Additional current focusing can be provided along the electrode surface by the annular grooves 70 and 72. The temperature of the tissue surrounding the electrode initially increase in initial zones 74, 76 and 78. The elevated temperature zone then extends to two intermediate zones 80 and 82, as the zones from the grooves merge. Thereafter all of the elevated temperature zones merge to form the single oval zone lesion 84. Use of these current focusing grooves 70 and 72 produces a more symmetrical lesion.

[0036] Fig. 9 is a plane view of the spiral groove embodiment of the current density focusing electrode of this invention. In this embodiment, the electrode is also ground to a single current focusing sharp tip 86 without secondary sharp corners or edges which could also focus or crowd current. Additional current focusing can be provided along the electrode surface by at least one spiral or helical groove 88. The temperature of the tissue surrounding the electrode initially increase in the initial tip zone 90 and a spiral zone 92. The elevated temperature zone then extends to two intermediate zones 94 and 96, as the spiral zone 92 merges to form a single zone 96. Thereafter all of the elevated temperature zones merge to form the single oval zone lesion 98. Use of the spiral focusing groove 88 provides a more symmetrical lesion.

[0037] Fig. 10 is an exploded view of the RF ablation catheter assembly shown in Fig. 1. The upper handle plate 276 has two central slots 278 and 280 through which the electrode control slides 10 and 11 are attached to respective left electrode slide block 282 and right electrode slide block 284. Sleeve control slides 12 and 13 are attached through outer slots 286 and 288 to respective left sleeve slide block 290 and right sleeve slide block 292. Fiber optic receptor housing 30 is mounted on the proximal surface of the upper handle plate 276. The electrical receptor 294 is received in respective cavities 296 and 298 in the upper handle plate 276 and lower handle plate 300 attached thereto. The lower handle plate 300 has a central cavity 302 which accommodates the electrode and sleeve slide blocks and associated elements.

[0038] Microswitch activator blocks 304 (only left sleeve block shown) are connected to the sleeve slide blocks 290 and 292. They are positioned to actuate the microswitches 306 when the respective sleeve block (and sleeve attached thereto) have been advanced. The microswitches 306 hold the respective RF power circuits open until the respective sleeves are advanced to a position beyond the urethra wall and into the prostate to prevent direct exposure of the urethra to the energized RF electrodes. Extension of the sleeve 5 mm beyond the guide is usually sufficient to protect the urethra.

[0039] The tension-torque tube assembly 308 is mounted in the distal end of the housing in the receptor 310.

[0040] Fig. 11 is an isometric view of the adjuster block and tension tube assembly 308 of the RF ablation catheter shown in Fig. 10. The torque tube 312 extends from the torque coupler 314 through the twist control knob 316 to the stylet guide 6. Bending flexure of the torque tube 312 during use lengthens the path from the handle to the guide tip 6. To prevent a resulting retraction of the stylet sleeve and electrode components when the torque tube 312 is flexed, a tension tube 318 having a fixed length and diameter smaller than the inner diameter of the torque tube 312 is provided. The distal end of the tension tube 318 is securely attached to the stylet guide 6, and the proximal end 320 is secured to the adjuster block 322, for example by an adhesive. The axial position of the adjuster block 322 can be adjusted to ensure the stylets 8 are initially positioned just inside the outlet ports in the stylet guide 6. Torque coupler 314 is mounted on the coupler block 324. Twist control knob stop pin 326 extends into a grove (not shown) and limits rotation of the control knob 316.

[0041] Fig. 12 is a detailed view "A" of the distal end tension tube connections of the tension tube shown in Fig. 11. The tension tube 318 is securely connected to the proximal end 328 of the stylet guide 6, for example by a length of shrink tubing 330.

[0042] Fig. 13 is an exploded view of the sleeve and electrode slide block assembly of the embodiment shown in Fig. 10. The right sleeve slide block 292 has a projection 332 which extends inward under the right electrode slide block 284. Right sleeve connector 334 is mounted to the inner end of the projection 332, secured to the end of the proximal end of the sleeve 336. Right electrode connector 338 is attached to an inner surface of the electrode slide block 284 and is secured to the proximal end of electrode 340. The right sleeve and electrode slide blocks 292 and 284 are slidingly attached to the right friction adjustment rail 342 by screws (not shown) through slots 348 and 346, the screws being adjustable to provide sufficient friction between the blocks and the rail 342 to provide secure control over the stylet movement. The left sleeve slide block 290 and left electrode slide block 282 are mirror replicas of the right blocks and are similarly mounted on the left friction rail 344. The left sleeve and electrodes are not shown.

Claims

1. A medical probe device for medical treatment of tissue at a treatment site in a body accessible through a natural body lumen defined by a wall and opening outside the body to provide a natural body opening comprising a catheter (2) having proximal and distal extremities and having a passageway (28) extending from the proximal extremity to the distal extremity, a flexible stylet (8) slidably mounted in the passageway, the distal extremity of the catheter having a stylet guide housing (6) having at least one stylet port and stylet guide means in communication with the passageway for directing the stylet sidewise of the catheter, the stylet including an insulating sleeve (30) having proximal and distal extremities and having an electrode lumen (50) terminating in a distal port at the distal extremity of the insulating sleeve, a radio frequency electrode (32) being positioned in the electrode lumen for longitudinal movement therein, a handle (4) coupled to the proximal extremity of the catheter for introducing the distal extremity of the catheter into the natural body opening to a position adjacent the treatment site, the handle including means (334,338,10,11,12,13) for advancing the stylet to cause the tip of the radio frequency electrode to penetrate the wall and extend into the tissue at the treatment site with the insulating sleeve extending through the wall, means (16) for supplying radio frequency energy to the radio frequency electrode to cause a thermal effect in the tissue at the treatment site while the insulating sleeve protects the wall from the thermal effect caused by the radio frequency energy, the insulating sleeve being provided with a second lumen (60) extending from the proximal extremity to the distal extremity of the insulating sleeve.

2. A medical probe device as in Claim 1 wherein a third lumen (58) is provided in the insulating sleeve that terminates in a sealed closure adjacent the distal end of the insulating sleeve and in which lumen a temperature sensing means (64) is provided which is positioned at the distal extremity of the insulating sleeve.

3. A medical probe device as in Claim 2 wherein an additional temperature sensing means (66) is disposed in the second lumen (60) of the insulating sleeve (30), the additional temperature sensing means (66) being spaced proximally from said first temperature sensing means (64) whereby, when the insulating sleeve is disposed in the wall, said first temperature sensing means monitors the temperature of the tissue surrounding the radio frequency electrode (32) and the additional temperature sensing means monitors the temperature of the wall.

4. A device as in Claim 2 wherein the inner surface of the electrode lumen is spaced from the outer surface of the radio frequency electrode (32) to define an additional liquid supply duct with an approximate annular cross section.

5. A medical device as in Claim 2 wherein the insulating sleeve (30) is provided with a third lumen (58) extending from the proximal extremity to the distal extremity of the insulating sleeve spaced apart from the second lumen (60).

6. A medical probe device as in Claim 1 wherein means (334,338,10,11,12,13) is carried by the handle (4) for causing relative movement between the insulating sleeve and the radio frequency electrode.

7. A medical probe device as in Claim 1 wherein the radio frequency electrode (32) has a distal length provided with at least one current focusing groove (70) thereon, the tip (68) being shaped to focus current on its terminal end whereby radio frequency current passing therefrom into surrounding tissue forms a lesion extending outward from the groove and tip.

8. A medical probe device as in Claim 7 wherein the distal length of the radio frequency electrode (32) is provided with a plurality of annular focusing grooves (70,72) thereon.

9. A medical probe device as in Claim 7 wherein the distal length of the radio frequency electrode (32) is provided with a spiral focusing groove (88) thereon.

Patentansprüche

1. Medizinische Sondenvorrichtung zur medizinischen Behandlung von Gewebe an einer Behandlungsstelle in einem Körper, die über ein natürliches Körperlumen zugänglich ist, das durch eine Wand definiert ist und sich in Bezug auf den Körper nach außen öffnet, wodurch eine natürliche Körperöffnung entsteht, umfassend einen Katheter (2) mit einem proximalen und einem distalen Ende, der einen Durchgang (28) aufweist, der sich vom proximalen Ende zum distalen Ende erstreckt, einen flexiblen Katheterdrain (8), der so im Durchgang montiert ist, dass er darin gleiten kann, wobei das distale Ende des Katheters ein Katheterdrain-Führungsgehäuse (6) aufweist, das zumindest eine Katheterdrain-Öffnung und ein Katheterdrain-Führungsmittel aufweist, das sich mit dem Durchgang in Kommunikation befindet, um den Katheterdrain in Bezug auf den Katheter zur Seite zu lenken, wobei der Katheterdrain eine Isolierhülle (30)

umfasst, die ein proximales und ein distales Ende aufweist sowie ein Elektrodenlumen (50) aufweist, das in einer distalen Öffnung am distalen Ende der Isolierhülle endet, wobei eine Radiofrequenzelektrode (32) so in, Elektrodenlumen angeordnet ist, dass sie sich in Längsrichtung darin bewegen kann, einen Griff (4), der an das proximale Ende des Katheters gekoppelt ist, um das distale Ende des Katheters bis zu einer Position in die natürliche Körperöffnung einzuführen, die an die Behandlungsstelle angrenzt, wobei der Griff Mittel (334, 338, 10, 11, 12, 13) umfasst, um den Katheterdrain vorwärts zu bewegen, um zu bewirken, dass die Spitze der Radiofrequenzelektrode die Wand durchdringt und sich an der Behandlungsstelle in das Gewebe erstreckt, wobei sich die Isolierhülle durch die Wand erstreckt, Mittel (16) zum Zuführen von Radiofrequenzenergie zur Radiofrequenzelektrode, um im Gewebe an der Behandlungsstelle eine thermische Wirkung zu verursachen, während die Isolierhülle die Wand vor der thermischen Wirkung schützt, die durch die Radiofrequenzenergie verursacht wird, wobei die Isolierhülle mit einem zweiten Lumen (60) versehen ist, das sich vom proximalen Ende zum distalen Ende der Isolierhülle erstreckt.

2. Medizinische Sondenvorrichtung nach Anspruch 1, worin in der Isolierhülle ein drittes Lumen (58) vorgesehen ist, das in einem abgedichteten Verschluß in Nachbarschaft des distalen Endes der Isolierhülle endet und in dem ein Temperaturfühlermittel (64) vorgesehen ist, das am distalen Ende der Isolierhülle angeordnet ist.

3. Medizinische Sondenvorrichtung nach Anspruch 2, worin ein zusätzliches Temperaturfühlermittel (66) im zweiten Lumen (60) der Isolierhülle (30) angeordnet ist, wobei das zusätzliche Temperaturfühlermittel (66) proximal vom erstgenannten Temperaturfühlermittel (64) beabstandet ist, wodurch, wenn die Isolierhülle in der Wand angeordnet ist, das erstgenannte Temperaturfühlermittel die Temperatur des die Radiofrequenzelektrode (32) umgebenden Gewebes überwacht und das zusätzliche Temperaturfühlermittel die Temperatur der Wand überwacht.

4. Vorrichtung nach Anspruch 2, worin die Innenfläche des Elektrodenlumens von der Außenfläche der Radiofrequenzelektrode (32) beabstandet ist, so dass eine zusätzliche Flüssigkeitszufuhrleitung definiert wird, die einen in etwa ringförmigen Querschnitt aufweist.

5. Medizinische Vorrichtung nach Anspruch 1, worin die Isolierhülle (30) mit einem dritten Lumen (58) versehen ist, das sich in einem Abstand vom zweiten Lumen (60) vom proximalen Ende zum distalen Ende der Isolierhülle erstreckt.

6. Medizinische Sondenvorrichtung nach Anspruch 1, worin ein Mittel (334, 338, 10, 11, 12, 13) vom Griff (4) getragen wird, um Relativbewegung zwischen der Isolierhülle und der Radiofrequenzelektrode zu bewirken.

7. Medizinische Sondenvorrichtung nach Anspruch 1, worin die Radiofrequenzelektrode (32) eine distale Länge aufweist, die mit zumindest einer Stromfokussierungsrille (70) darauf versehen ist, wobei die Spitze (68) so geformt ist, dass sie Strom auf ihrem Endpunkt fokussiert, wodurch Radiofrequenzstrom, der daraus in das umgebende Gewebe gelangt, eine Läsion bildet, die sich von der Rille und Spitze nach außen erstreckt.

8. Medizinische Sondenvorrichtung nach Anspruch 7, worin die distale Länge der Radiofrequenzelektrode (32) mit einer Vielzahl ringförmiger Fokussierungsrillen (70, 72) darauf versehen ist.

9. Medizinische Sondenvorrichtung nach Anspruch 7, worin die distale Länge der Radiofrequenzelektrode (32) mit einer spiralförmigen Fokussierungsrille (88) darauf versehen ist.

Revendications

1. Dispositif à sonde médicale pour le traitement médical de tissus à un site de traitement dans un corps accessible à travers une lumière naturelle du corps définie par une paroi et une ouverture à l'extérieur du corps afin de procurer une ouverture naturelle du corps, comprenant un cathéter (2) ayant des extrémités proximale et distale et ayant un passage (28) s'étendant de l'extrémité proximale à l'extrémité distale, un stylet flexible (8) monté de manière permettant le coulissement dans le passage, l'extrémité distale du cathéter ayant un logement de guidage du stylet (6) comportant au moins une porte de stylet et un moyen de guidage de stylet en communication avec le passage pour diriger le stylet sur le côté du cathéter, le stylet incluant un manchon d'isolation (30) ayant des extrémités proximale et distale et ayant une lumière d'électrode (50) se terminant par une porte distale à l'extrémité distale du manchon d'isolation, une électrode de radiofréquence (32) étant positionnée dans la lumière d'électrode pour effectuer un mouvement longitudinal dans celle-ci, une poignée (4) couplée à l'extrémité proximale du cathéter pour introduire l'extrémité distale du cathéter dans l'ouverture naturelle du corps vers une position adjacente au site de traitement, la poignée comprenant des moyens (334, 338, 10, 11, 12, 13) pour

faire avancer le stylet de façon à amener l'extrémité de l'électrode de radiofréquence à pénétrer dans la paroi et s'étendre dans le tissu au site de traitement, le manchon d'isolation s'étendant à travers la paroi, des moyens (16) pour apporter de l'énergie de radiofréquence à l'électrode de radiofréquence afin de provoquer un effet thermique dans le tissu au site de traitement tandis que le manchon d'isolation protège la paroi de l'effet thermique provoqué par l'énergie de radiofréquence, le manchon d'isolation étant pourvu d'une deuxième lumière (60) s'étendant de l'extrémité proximale à l'extrémité distale du manchon d'isolation.

2. Dispositif à sonde médicale suivant la revendication 1, dans lequel une troisième lumière (58) est prévue dans le manchon d'isolation et se termine par une fermeture scellée adjacente à l'extrémité distale du manchon d'isolation et dans laquelle lumière un moyen de détection de la température (64) est prévu, lequel est positionné à l'extrémité distale du manchon d'isolation.

3. Dispositif à sonde médicale suivant la revendication 2, dans lequel un moyen supplémentaire de détection de la température (66) est disposé dans la deuxième lumière (60) du manchon d'isolation (30), le moyen supplémentaire de détection de la température (66) étant espacé de manière proximale du premier moyen mentionné de détection de la température (64), le premier moyen mentionné de détection de la température surveillant la température du tissu entourant l'électrode de radiofréquence (32) et le moyen supplémentaire de détection de la température surveillant la température de la paroi lorsque le manchon d'isolation est disposé dans la paroi.

4. Dispositif suivant la revendication 2, dans lequel la surface intérieure de la lumière d'électrode est espacée de la surface extérieure de l'électrode de radiofréquence (32) afin de définir un conduit supplémentaire d'apport de liquide avec une section transversale approximativement annulaire.

5. Dispositif médical suivant la revendication 1, dans lequel le manchon d'isolation (30) est pourvu d'une troisième lumière (58) s'étendant de l'extrémité proximale à l'extrémité distale du manchon d'isolation en étant espacée de la deuxième lumière (60).

6. Dispositif à sonde médicale suivant la revendication 1, dans lequel des moyens (334, 338, 10, 11, 12, 13) sont portés par la poignée (4) pour provoquer un mouvement relatif entre le manchon d'isolation et l'électrode de radiofréquence.

7. Dispositif à sonde médicale suivant la revendication 1, dans lequel l'électrode de radiofréquence (32) a une longueur distale pourvue sur celle-ci d'au moins une rainure de focalisation du courant (70), l'extrémité (68) étant formée de façon à focaliser le courant à son extrémité terminale, le courant de radiofréquence passant de celle-ci dans les tissus environnant formant une lésion s'étendant à l'extérieur de la rainure et de l'extrémité.

8. Dispositif à sonde médicale suivant la revendication 7, dans lequel la longueur distale de l'électrode de radiofréquence (32) est pourvue sur celle-ci d'une pluralité de rainures de focalisation annulaires (70, 72).

9. Dispositif à sonde médicale suivant la revendication 7, dans lequel la longueur distale de l'électrode de radiofréquence (32) est pourvue sur celle-ci d'une rainure de focalisation spiralée (88).

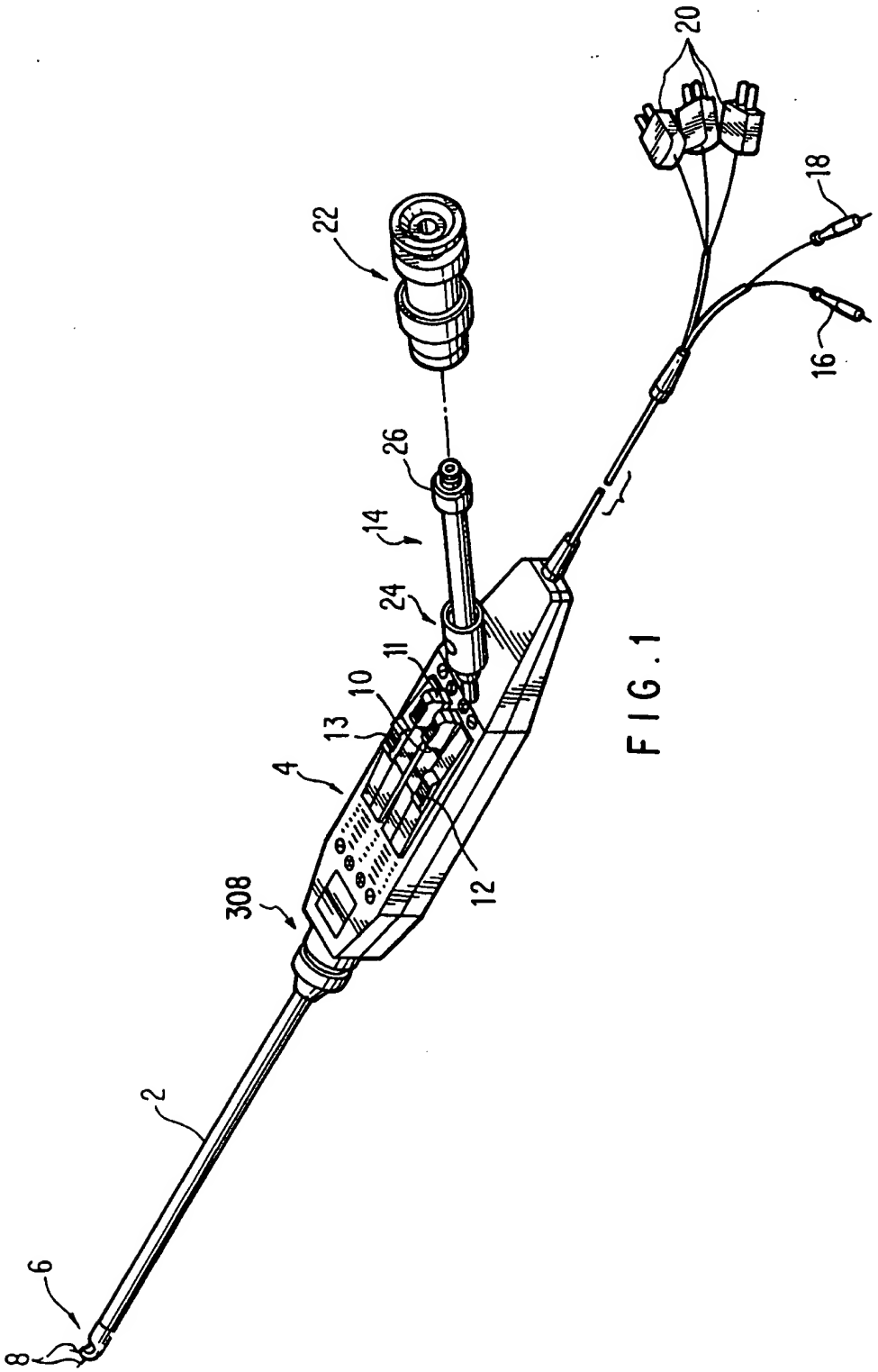

FIG.1

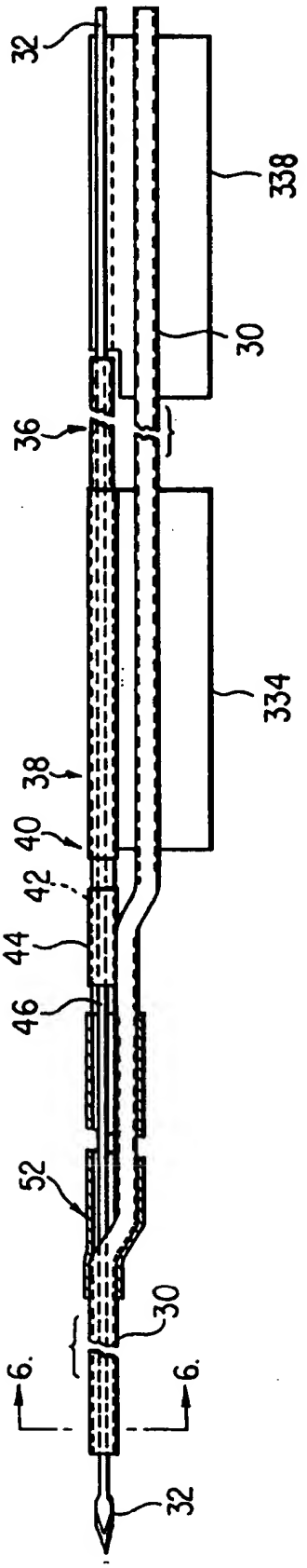

FIG. 3

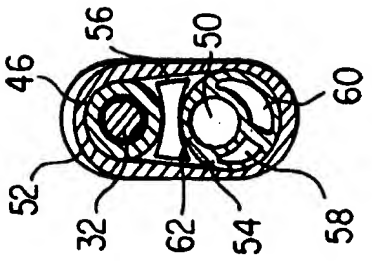

FIG. 5

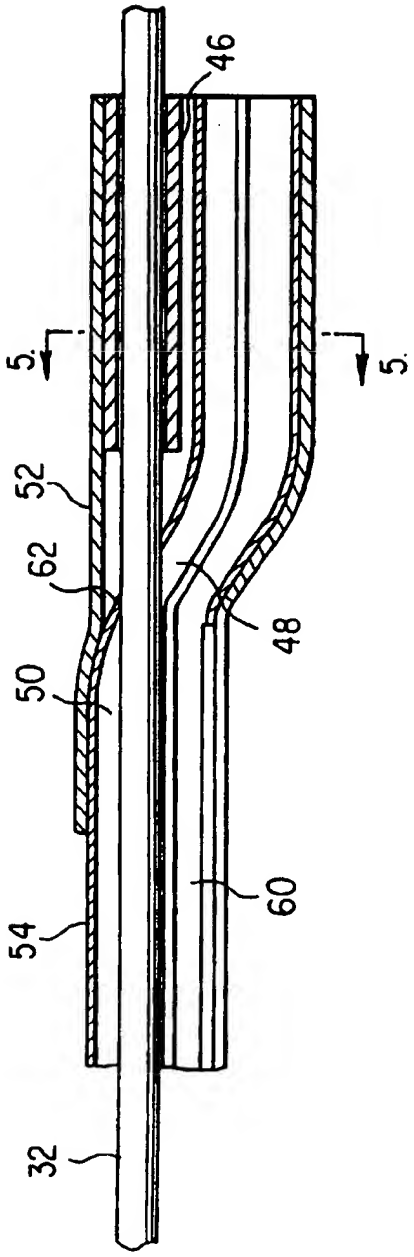

FIG. 4

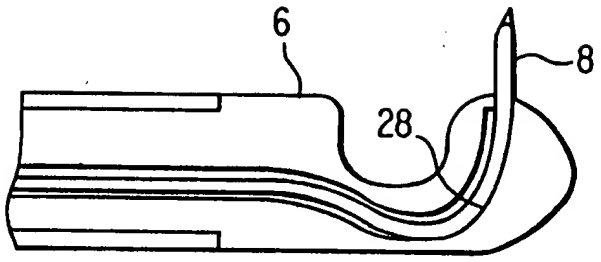

FIG. 2

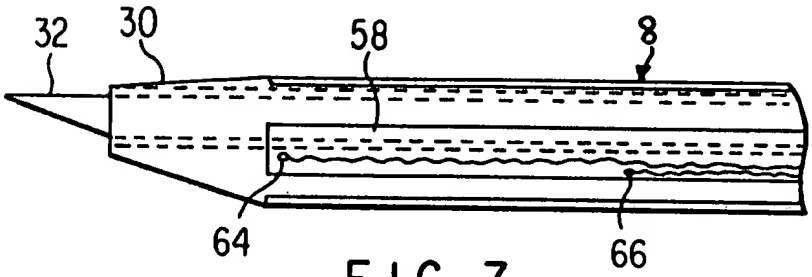

FIG. 7

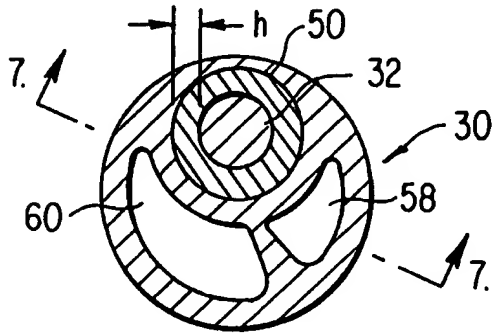

FIG. 6

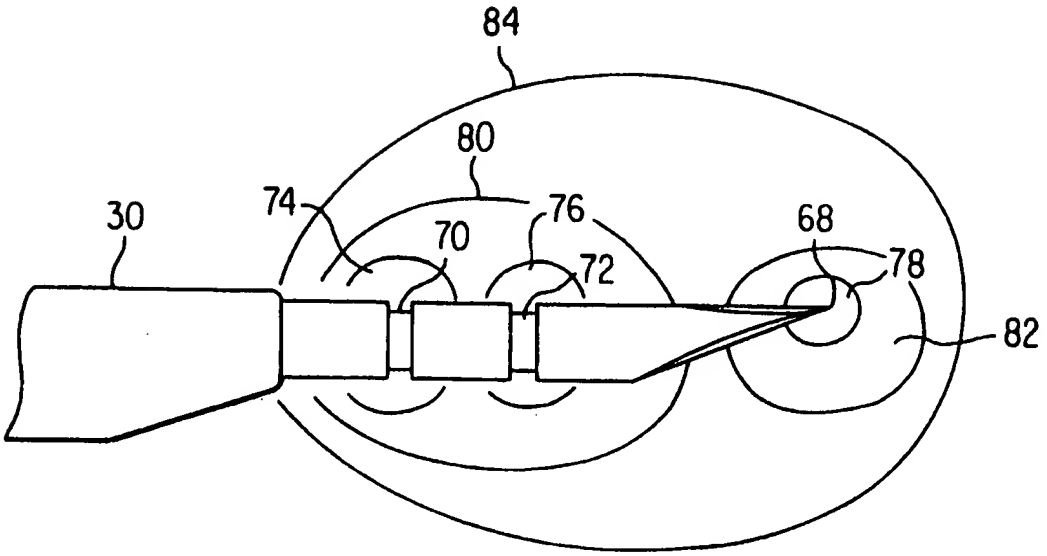

FIG. 8

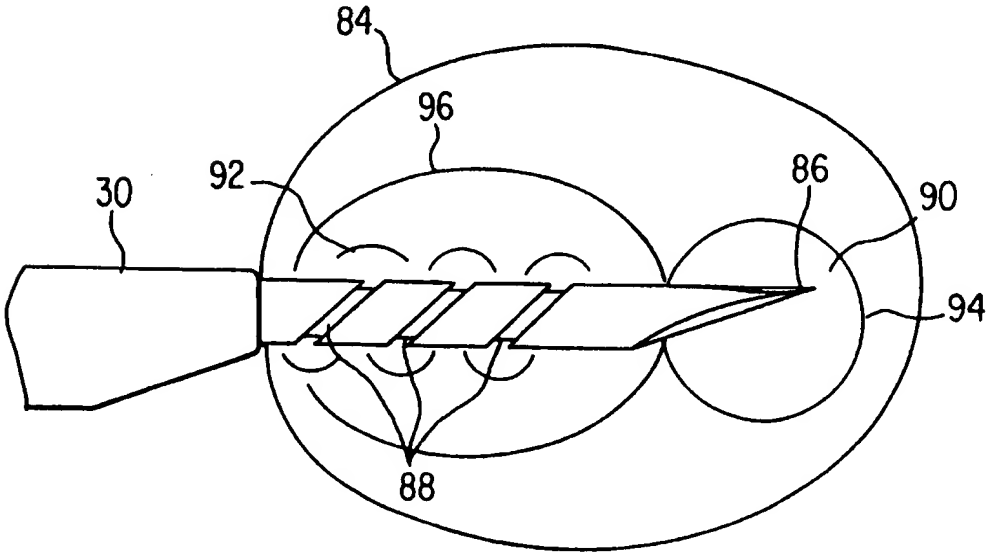

FIG. 9

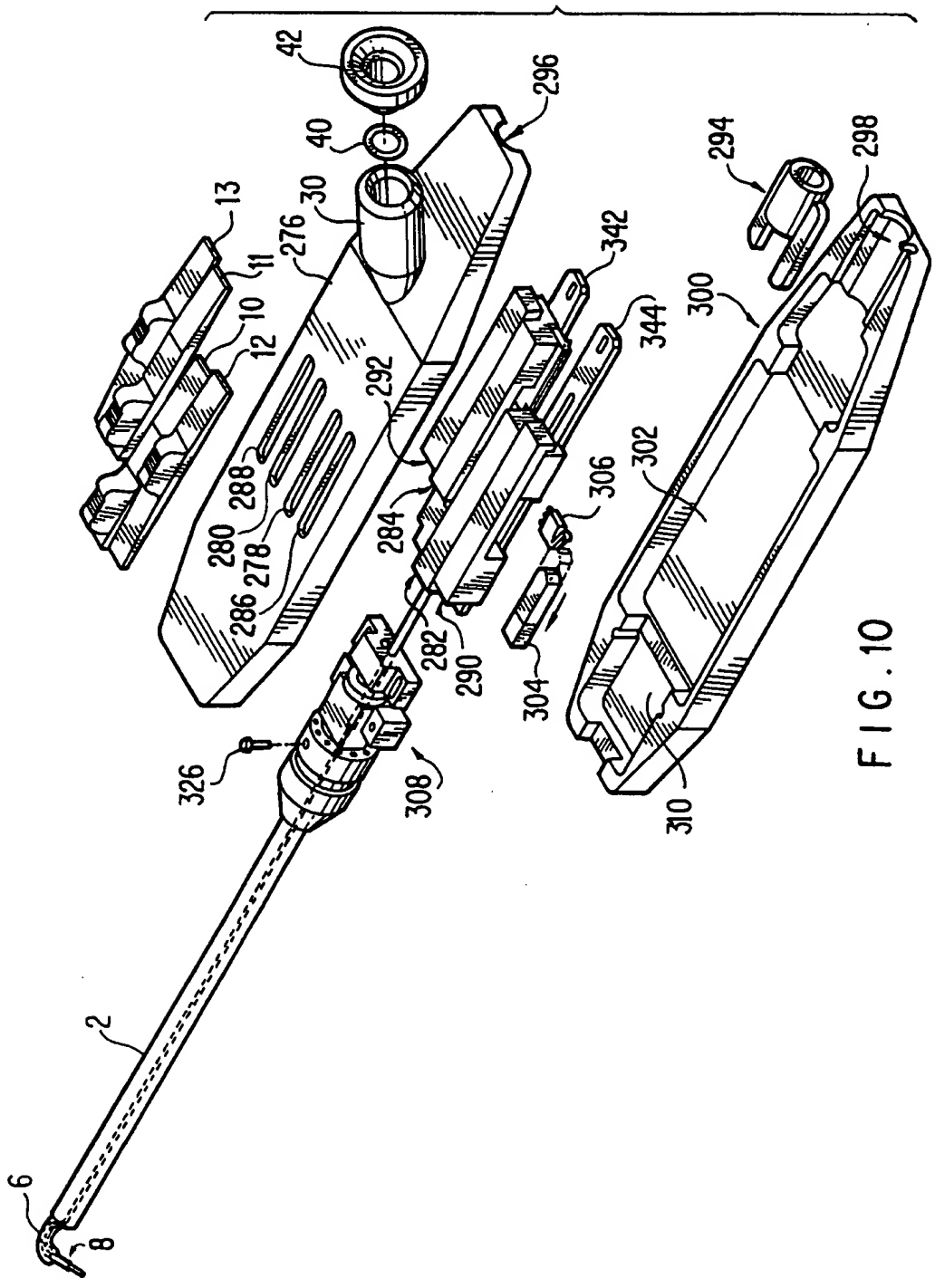
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FIG. 10

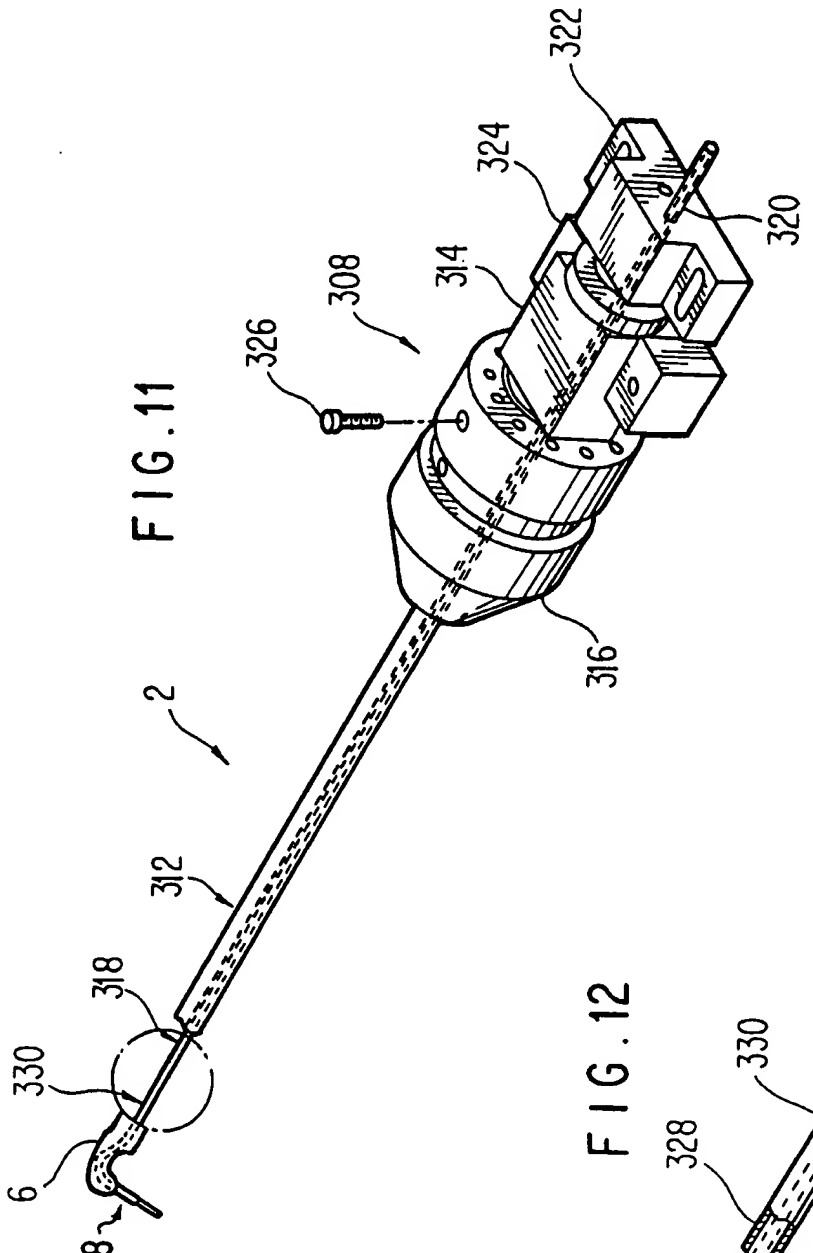

FIG. 11

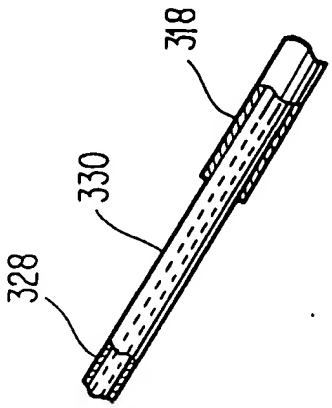

FIG. 12

FIG. 13